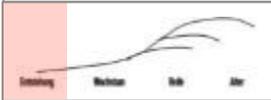


Technology Profile 1/4 (Status)

The Status chart explains the technology, its research status, life cycle stage and its expected business potential

Technology Description	<p>Orputec has developed a device that uses the technology of a <u>pulse-synchronous alternating pressure system</u>. It can be applied in the field of regenerative medicine to treat lymphedema by improving the blood- and lymphatic circulation. The machine consists of four components: an electrocardiograph (ECG), a vacuum pumps, a software computing the timing of suction and drainage, and an individual suction cap for each patient.</p> <p>First of all, the pulse is measured by the ECG to estimate when the blood pressure is at its maximum. This point of time is then passed on to the vacuum pump. Receiving the signal, the pump starts to generate a pulse-synchronous underpressure at the suction cap, which is placed on the affected tissue. During the <u>suction phase</u>, oxygen and nutritive substances are drawn in to the vessel and the tissue, while during the <u>drainage phase</u> the blood flows back through the veins to the heart.</p> <p>Thus, the supply of the tissue with blood and lymph is improved, while the body's own mechanisms of regeneration are systematically supported.</p> <p>This combination not only treats the tissue with great care, but also facilitates optimal blood circulation, thereby making the pulse-synchronized alternating pressure system particularly efficient and unique in the market.</p>	
	<p>The technology of the pulse-synchronous alternating pressure system has been originally developed for wound management and was patented by Mr. Schleusener, one of the founders of Orputec. It is ready for application. Prototypes are being tested with patients on a small scale and provide first promising results. Current efforts concentrate on the preparation of a larger clinical study, the medical certification and design issues before market entry.</p>	
Research Status	<p>With about 80.000 patients faced with lymphedema and requiring lifelong treatment in Germany, efficient therapies offer promising business perspectives. Direct customers of Orputec will be hospitals and clinics, but also smaller medical practices, physiotherapists and medical supply stores, who can then offer a more efficient treatment for patients. The current therapies for the condition include compression hosiery, manual lymphatic drainage and equipment based lymphatic drainage, using garments administering overpressure and, more rarely, larger tube in which the patients are treated with underpressure. Although the existing machines can offer therapeutic success, they have certain disadvantages: the corresponding garments are large and unwieldy to use, the applied overpressure is not as gentle to the tissue on hand, and all the existent devices have a considerable size and price. Orputec provides an attractive substitute which has a more gentle underpressure approach, is smaller and easier to handle while also costing less. The expected price is at 10.000€. Assuming a physician earns 50€ per therapy session, only 200 of those sessions are necessary to break even.</p> <p>In order to be used on patients, the device has to receive medical certifications in line with ISO standards from the TÜV. The market can then be entered in two ways – either by offering the therapy as an individual service for which patients have to pay (“Individuelle Gesundheitsleistung IGeL”), or by being accepted in the statutory and/or private health insurances’ portfolio of paid-for treatments (“Kassenleistung”). The latter allows to reach a broader mass but getting the insurances on board will be a long and complex process which also requires a successful clinical study.</p> <p>As the health care industry is dominated by a few big players, a cooperation with a well established partner would be very advantageous. It still has to be decided whether the partnership will involve support in the process of medical licensing and the clinical study or whether the focus will be on production and distribution. In any case, the manufacturing of the individual pick cap for each patient will be handled by Orputec, providing an additional income stream. In terms of current and further application fields, wound management and lymphatic drainage are only two of many conceivable utilizations of the pulse-synchronous alternating pressure system. The gentle improvement of the blood flow might also be interesting in the beauty and wellness sectors, for example for the treatment of wrinkles, cellulitis or weak veins and the stimulation of the metabolism.</p>	
	<p>The technology of the pulse-synchronous alternating pressure system has been originally developed for wound management and was patented by Mr. Schleusener, one of the founders of Orputec. It is ready for application. Prototypes are being tested with patients on a small scale and provide first promising results. Current efforts concentrate on the preparation of a larger clinical study, the medical certification and design issues before market entry.</p>	
Business Potential	<p>Barriers to access</p> <p>licenses</p>	
	<p>Introduction</p> 	

Technology Profile 2/4 (Players)

The Players chart shows current and recent activities of the most important actors around this technology

Active Players		Activities
MEDCERT, TÜV SÜD CERT, TÜV NORD CERT	<p>Technical Inspection Authorities</p> <p>high</p>	 <p>Technical inspection authorities are, according to § 15 (1) Medical Devices Act, labelled agencies and thus authorized to issue medical devices licenses, certifying the compliance to ISO 13485 and the guideline 93/42/EW. Thus they are the first major bottleneck, because the success of launching Orputec's device as an medical device seriously depends on their judgement and could heavily delay or even hinder the market entrance.</p>
TK, AOK, BKK, IKK, DAK, HUK Coburg, DKV, Debeka,	<p>Health Insurances</p> <p>high</p>	 <p>Health insurances are the other important bottleneck, since they decide whether to accept the treatment of lymphedema with Orputec's device in their catalogue of paid-for therapies. It is however important to note, that statutory health insurances play an even more significant role than private health insurances, because when they determine that the device will be made available and reimbursable for the patients, this will enable Orputec to reach the mass market, thereby facilitating the device's success and broad effect.</p>
Bayer, Siemens, Fresenius MedCare	<p>Industry Cooperation Partners</p> <p>high</p>	 <p>Industry cooperation partners play an important role in the successful launch of the medical device, because a cooperation could aid to survive and successfully meet the often financially challenging growth phase, by providing financial aid, undertake the marketing and also provide valuable advise and network ties.</p>
Helios, Rhön, Asklepios; Citipraxen	<p>Private clinics, doctors' & physiotherapists' offices</p> <p>high</p>	 <p>Since clinics, doctors and physiotherapist offices can be seen as Orputec's main customers and are in direct contact with the patients, they play an active role in the technology's successful launch and consumer adoption. In focus should be especially private clinics and doctors, since they often have larger budgets at their disposal and the autonomy of deciding which devices to buy and apply.</p>
Local Physiotherapists; Xilia Press, Vacumed, Bösl Medizintechnik, Tactile Systems Technology, Bio Compression Systems	<p>Competitors</p> <p>medium</p>	 <p>The most common method for lymphatic drainage has been the manual massage by physiotherapists. However, other companies have also developed technical devices and established a strong presence on the market, which they serve with already licensed substitutes, thereby addressing the same needs as Orputec's device. However since they use different technologies such as intermittent pneumatic compression or intermittent negative pressure, Orputec has to emphasize the advantages of its product working with a pulse-synchronous alternating pressure technology.</p>
Fraunhofer Institute, Max-Planck-Institute, KIT Institute & Uniklinik Eppendorf, Charité etc.	<p>Teaching Hospitals, Universities & Research Institutes</p> <p>medium</p>	 <p>Teaching Hospitals, universities and research institutes also take an active role in further developing the technology on hand, since they drive the regenerative medicine industry's R&D topics and build upon clinical studies to further leverage the findings and to advance existing technologies in this field. New developments can prove to be beneficial to Orputec but also boost competition and new market entry by additional players.</p>

Technology Profile 3/4 (Drivers)

The Drivers chart explains the 5-6 most important key drivers for the technology's further evolution

Success of the clinical study

The efficiency and success of the treatment of lymphedema are crucial drivers of Orputec's development. The further steps and the acceptance of all stakeholders depend on whether the therapy is improving the patients' condition. A clinical study is one of the pivotal factors for receiving the necessary medical certification as well as for being accepted by the health insurances. As it shows the device's effectiveness and reliability, the clinical study also provides concrete arguments for convincing doctors, patients and possible cooperation partners.



Quality of resources & material

As Orputec is offering a physical product, the quality of the used material is essential. It has to be durable and approved for medical use. The constructing of the vacuum pump, the suction cap and the programming of the software have to comply with high quality standards to ensure the success of the treatment as well as of the medical certification. Good relations to trusted suppliers are therefore especially important.



Health insurance acceptance

Health insurances play an important role in reaching the mass market. If the insurances accept the treatment of lymphedema with Orputec's device in their catalogue of paid-for therapies, a much larger impact than with the "IGeL" is possible. However, the process of convincing the health insurances can be characterized as complex, heterogeneous and sometimes intransparent. Additionally, two kinds of health insurances exist: the statutory and private ones. As for the statutory health insurances, a central committee decides upon the admission of the device, whereas private health insurance decide this individually.



Product advantages

Orputec's device has to stand out from the existing methods for treating lymphedema. Its effectiveness is the first distinguishing factor. Other advantages are the superior usability due to the smaller size and the lower price. Both allow Orputec to reach a wide range of customers, including also smaller practices and medical supply stores which might rent the device to patients. Focusing on those benefits and communicating them to health insurances, hospitals, doctors and patients will allow Orputec to establish a strong market position.



Acquisition of medical certification

The intended use of Orputec's device, the treatment of lymphedema, is a medical procedure and therefore has to comply with German and international norms. The relevant standards to achieve regulatory approval are DIN EN ISO 13485 and DIN EN ISO 9001 which proofs the manufacturing under a certain quality management system, as well as DIN EN ISO 14971 which establishes risk management requirements for medical devices. Getting the necessary external institutional validation is the bottleneck that has to be passed in order to be able to go to the market.



Technology Profile 4/4 (Summary)

The Summary chart provides an integrated overview of the technology, business potential, drivers, and players



Video: Suction cap in action

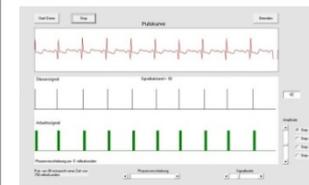
Click here to view: <http://www.orthos-hamburg.de/uploads/media/Absaugkappe.avi>

Orputec's new device is using a pulse-synchronous alternative pressure system for a more efficient treatment for lymphedema.

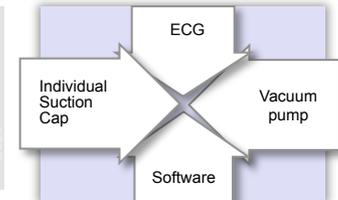
The device consists of four components: an electrocardiograph (ECG), a vacuum pumps, a software computing the timing of suction and drainage, and an individual suction cap for each patient. Synchronously with the patients pulse, the suction cap on the affected tissue generates an underpressure provided by the vacuum pump that improves blood and lymph flow, thereby supporting the body in regenerating itself.

The technology of the pulse-synchronous alternating pressure system has been patented. It is ready for application. Prototypes are being tested with patients on a small scale and provide first promising results.

Activities & Players



Pulse and administered underpressure are synchronous



Technical Requirements

Business Potential

- The pulse-synchronous alternative pressure system is unique in the market and provides an innovative approach to treating lymphedema. With a therapy device that is gentle to the tissue, smaller in size and easier to use while also costing less than other treatments, Orputec faces many promising business opportunities.
- Current competing therapies include compression hosiery, manual lymphatic drainage and equipment based lymphatic drainage. The latter use either garments administering overpressure or larger tube in which the patients are treated with underpressure. Although the existing machines can offer therapeutic success, they are large and unwieldy to use, not as gentle, and have a considerable price.
- The number of patients suffering from lymphedema amounts to about 80.000 in Germany. They need lifelong and diligent treatment. However, Orputec's direct and main customers are hospitals, clinics, doctors and physiotherapists who serve as intermediaries and multipliers for many patients.
- Medical certification is a necessary step before entering the market. To exploit the full business potential, the acceptance of the health insurances is crucial.

Key Drivers

- Quality of resources and the used material determine the device's ABBC
- Success of the clinical study are crucial for the application and acceptance
- Product advantages compared to existing treatments have to be conveyed clearly
- The acquisition of the medical certification is an essential step in order to sell the device in the healthcare market
- The health insurances' acceptance of Orputec's device as a treatment for which they cover the costs is key to reach a mass market

1 Technical Inspection Authorities (MEDCERT, TÜV SÜD CERT, TÜV NORD CERT) – are labelled agencies that issue medical device licenses and are the first bottleneck



2 Health Insurances (TK, AOK, BKK, ...) – decide to accept the treatment of lymphedema with Orputec's device in their catalogue of paid-for therapies



3 Industry Cooperation Partners (Bayer, Siemens, Fresenius MedCare) – offer potential financial, marketing and network aid during the growth phase



4 Private clinics, doctors' & physiotherapist offices (Helios Clinics, Rhön Clinics...) – are Orputec's direct customer and strongly influence the product's market establishment



5 Physiotherapists and Competitors (Vacumed, Bösl Medizintechnik...) – are established players in the market of lymph drainage, however use different technologies

